REMARKS

Claims 1-25 are currently pending in the above-identified application. Applicants have amended claims 1, 8, 10, 15, 21-23. Applicants have added claims 26-27, and canceled claim 11.

Claim 10 stands rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Claims 1-3, 5, 7-11, 14-17, 19, and 21-23 stand rejected under 35 U.S.C. 102(e) as allegedly being anticipated by U.S. Patent No. 6,319,230 to Palasis et al. Claims 4, 6, 12, 13, 18, 20, 24, and 25 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Palasis et al. in view of U.S. Patent No. 5,758,663 to Wilk et al.

As set out in more detail below, Applicants submit that the pending claims, as amended, are patentably distinct from the cited art and, consequently, requests allowance of each of the pending claims in light of the foregoing amendments and following remarks.

Objections to the Specification

The Examiner referenced claim 13 in objecting to the specification as "failing to provide proper antecedent basis for the claimed subject matter." *See* Office Action, p. 2, ¶2. Applicants have amended paragraph [0020] of the application to clearly identify the antecedent basis in the specification for nomenclature used in the as-filed original claims. This amendment to the specification does not introduce new matter to the disclosure.

The Claims, as Amended, Overcome the 35 U.S.C. §112 Rejection

Claim 10 stands rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Applicants have amended the claims to recite "therapeutic material" to obviate this rejection. Support for the amended language can be found at least in ¶¶ [0018], [0030] through [0032], [0034], [0042], [0043], and [0049] of the application, all of which recite examples of therapeutic material (such as therapeutic proteins, among others) that is injected into tissue for treatment. As stated in ¶ [0018], the injection catheter device is used to "deliver therapeutic and in-situ plug forming material to a target site." The therapeutic may also be in a polymer solution. *See* Application, ¶ [0030]. Thus, the use of the term "therapeutic" in the specification is

synonymous and consistent with the meaning of a "therapeutic material," and this amendment to the specification does not introduce new matter to the disclosure.

The Claims, As Amended, Are Patentably Distinct Over Palasis

Claims 1-3, 5, 7-11, 14-17, 19, and 21-23 stand rejected under 35 U.S.C. 102(e) as allegedly being anticipated by U.S. Patent No. 6,319,230 to Palasis et al. Applicants respectfully submit that the claims are patentable over the Palasis reference because Palasis does not disclose or suggest the limitation of a channel "in fluid communication with a plug forming material," as recited in each of the amended independent claims. Palasis does not suggest a plug made from plug forming material to seal the injected fluid within the tissue. Rather, Palasis discloses using injection needles orthogonal to the "direction of penetration of the primary penetrating member ... [so] the fluid will be retained within the heart tissue." *See* Palasis, col. 7:38-41; Figs. 1B, 2, 6C, 7C. Further, the suction head of Palasis teaches away from forming a seal to retain the injected fluid in the dynamic heart muscle by applying a vacuum to the suction head that would draw the injectate out of the tissue instead of sealing the injected fluid within the tissue. *See* Palasis, col. 8:11-17.

The Claims, As Amended, Are Patentably Distinct Over Palasis In View Of Wilk

Claims 4, 6, 12, 13, 18, 20, 24, and 25 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Palasis et al. in view of U.S. Patent No. 5,758,663 to Wilk et al. Applicants respectfully submit that, for the same reasons stated above, the claims are patentably distinct over Palasis in view of Wilk because neither reference discloses or suggests at least the limitation of a channel "in fluid communication with a plug forming material." The Wilk reference generally regards coronary or gastrostomy tubular by-pass members and is referenced in the Office Action to teach the use of "biocompatible adhesive on a cardiovascular device ... to adhere a device to a patient's tissue." *See* Office Action, p. 3, ¶8. Wilk does not disclose or suggest the use of a seal in association with its by-pass devices, which would defeat the purpose of the by-pass devices. Accordingly, Applicants respectfully submit that the claims are patentable over Palasis in view of Wilk.

CONCLUSION

In view of the preceding remarks, the Applicants respectfully assert that each of the pending claims are in condition for allowance and, therefore, request reconsideration and allowance of all pending claims.

The Commissioner is hereby authorized to charge Kenyon & Kenyon Deposit Account No. 11-0600 for any applicable fee.

Should the Examiner require any additional information regarding this Response, the Examiner is invited to contact the undersigned at (202) 220-4200.

Respectfully submitted,
KENYON & KENYON

Dated: 12/29/05

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